#### REMARKS

Claims 30-56 are pending in this Application. Claims 30-53 were rejected and claims 54-56 have been withdrawn from consideration. Claims 30, 33-35, 38, 40, 42, 43, 45-47 and 51 have been amended. Applicants request reconsideration of the rejected claims in view of the amendments and the following remarks, which address all of the issues raised in the Office Action.

## Claim Amendments

Claims 30, 33-35, 38, 40, 42, 43, 45-47, and 51 have been amended for clarity.

Claims 33, 34, 38 and 51 were also amended to provide antecedent basis for certain claim limitations. No new matter has been added.

# Objection to the Drawings

The drawings have been objected to under 37 C.F.R. § 1.83(a). The Office Action asserts that the drawings fail to show every feature of the invention that is specified in the claims. In particular, the Office Action asserts that the abutment, the anchorage part as a separate cylindrical component, and the dedicated features on the fixture head must be shown in the drawings or canceled from the claims. Applicants have submitted herewith replacement drawings that clearly point out these features. Specifically, the anchorage is shown as item A in Figure 1; the abutment is now labeled as item 22 in Figure 2; and the

dedicated feature is now labeled as item D in Figure 5. By this Reply, Applicants have also amended the description of Figure 5 on page 10 of the specification to be consistent with the amended drawing. The captions for Figures 1 and 2 were similarly amended in Applicants' prior office action response. An additional change to the caption for Figure 2 has also been made in this Reply. Support for the amended drawings and changes to the figure captions is found throughout the application. No new matter has been added. In view of these changes to the drawings and accompanying figure captions, Applicants respectfully submit that the objection to the drawings should be withdrawn.

## Rejections under 35 U.S.C. § 112

Claims 33-34, 38, and 44-51 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants traverse this rejection as applied to the amended version of the claims.

Claims 33 and 34 were rejected as lacking antecedent basis for the limitation "the threaded shaft." These claims have both been amended to recite that the retaining screw has "a threaded shaft" prior to the recitation of "the threaded shaft" later in the claim.

Thus these claims now contain proper antecedent basis for this term and the § 112 rejection of these claims may now be withdrawn.

Claim 38 was rejected as lacking antecedent basis for the limitation "the proximal surface." This claim has been amended to recite that the fixture head has "a proximal surface" prior to the recitation of "the proximal surface" later in the claim. Accordingly, claim 38 now contains proper antecedent basis for this term and the § 112 rejection of claim 38 may now be withdrawn.

Claim 51 was rejected for lack of antecedent basis for the limitations "the diameter of proximal" in line 2, "said two parts" in line 3, and "the distal part" also in line 3.

Claim 51 has been amended to recite that the internal shaft comprises "a proximal cylindrical part" and "a distal cylindrical part" thus providing proper antecedent basis for the other references to these limitations that appear in the claim. The § 112 rejection of claim 51 may now be withdrawn.

The Office Action also asserts that claims 44-51 are unclear because the independent claims 44, 48, and 49 recite certain "claimed elements", i.e. a retaining screw, an impression coping, and a burn-out cylinder, respectively, for use with or in combination with certain "non-claimed elements." However, claimed elements are often defined by reference to how those elements interact with, or are used with or affect other non-claimed elements. Thus, reference to such non-claimed elements alone does not make the claims unclear. This rejection should, therefore, be withdrawn.

#### Rejections under 35 U.S.C. § 103 citing Forsmalm

Claims 30-48 and 52-53 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Forsmalm et al. (U.S. Patent No. 5,584,694) either alone or in

combination with one or more secondary references (e.g., Gordon (U.S. Patent No. 5,733,122); Kumar et al. (U.S. Patent No. 6,447,295); Lazzara et al. (U.S. Patent No. 4,988,297); Gahlert (2005/0106534); and Bori (U.S. Patent No. 4,872,840)). Applicants respectfully traverse this rejection.

The present invention provides a dental implant-to-prosthesis interface that allows for lateral misalignments between the fixture heads of the implants and the connections to the prosthesis. Specifically, the invention features the combination of a dedicated implant, a prosthesis, and a retaining screw, wherein the anchorage part of the prosthesis comprises a hole for the retaining screw to pass through. The diameter of the neck of the retaining screw is sufficiently smaller than the diameter of the hole so as to allow for compensation of lateral misalignments between the center of the anchorage part of the prosthesis and the center of the implant or implant assembly during placement of the prosthesis onto the implant(s) in the patient's mouth. This is different from traditional implant-to-prosthesis interface systems in which the tolerances between the retaining screw and the hole are typically as small as possible, usually just enough to allow the screw to pass through the hole. By providing a screw with a neck portion with a greater magnitude of fitting tolerance than traditional systems, the present invention allows for the use of pre-manufactured prostheses for immediate loading onto the implant, as well as easier placement in situations where the prosthesis is anchored to multiple implants.

Forsmalm takes an entirely different approach for trying to address the problem of

misalignments between a dental prosthesis and an implant or implant assembly.

Forsmalm seeks to improve the precision of alignment between the prosthesis and implant(s) by minimizing errors in lateral alignment that can occur during the impression-taking stage, before the prosthesis has been created. To do this Forsmalm uses a conical shaped guide pin to center impression-taking components over the implant with improved accuracy. When the conical-shaped head (11) of the guide pin interacts with the edge (6''') of the stop on the impression-taking component (1) the contact force acts in both an axial and radial direction (col. 3, lines 16-56). This allows the component to be displaced in the appropriate direction as the edge of the stop slides along the edge of the conical-shaped guide pin until it is centered into place, thus resulting in a better alignment and more accurate placement of the impression-taking component relative to the fixture point of the implant.

Rather than trying to compensate for lateral misalignments between the prosthesis and the implant after the prosthesis has been made, Forsmalm seeks to avoid the introduction of misalignments before the prosthesis has been created through more accurate centering of impression components to assure that a good impression is taken. In contrast, the present invention allows for such misalignments to exist at the anchoring points of the prosthesis to the implant, and provides a means for correcting or compensating for these misalignments when the final prosthesis is fastened onto the implants. This concept is neither disclosed nor rendered obvious by Forsmalm.

The Office Action asserts that Figure 2a of Forsmalm shows a combination of a dedicated dental implant, a prosthesis comprising an anchorage part, and a retaining screw, wherein the anchorage part comprises a hole for the retaining screw and the diameter of the neck of the retaining screw is smaller than that of the hole in the anchorage part (see Office Action, p. 5). Applicants disagree. The apparatus depicted in Figure 2 of Forsmalm is for taking dental impressions rather than for placing a dental prosthesis onto implants in the mouth. Specifically, Figure 2a shows a guide pin (4) with a conical contact surface (11) that is used to help center an impression top (1) onto a distance member (2). The impression top is not a dental prosthesis. Rather, the impression top is for making an impression of the patient's dental situation from which a model is created and used to construct the prosthesis. Thus, the prosthesis has not even been created yet at this stage in the process. Indeed, all of the stages shown in Figs 2a-c are various steps of the impression-taking process, and do not illustrate the placement of a prosthesis onto the implant, i.e. these figures are not depicting a prosthesis-to-implant interface.

Although Forsmalm does discuss the eventual placement of a prosthesis onto the implant(s), this step is not the focus of the Forsmalm invention. Consequently, it is not shown in any of the drawings and very few details of the placement process are described. It is clear, however, that the guide pin shown in Figure 2a is only used during the impressioning process to center impression-taking components. It is not a retaining screw

used for placing the prosthesis onto the implant. Forsmalm clearly states that "in the fourth and final stage", i.e. the stage of anchoring the prosthetic construction into the patient's mouth, "a flat gold screw is used instead of the conical guide pin" (see also column 4, lines 25-32, which indicate that a "flat gold screw" is used when the final construction is anchored into the patient's mouth). No further details are provided about this screw, and it is not depicted in any of the figures. Thus, there is no teaching in Forsmalm that the retaining screw contains a neck (defined in the present specification as a non-threaded region) that has a diameter that is sufficiently smaller than the diameter of the hole in the anchorage part of the prosthesis to allow for compensation of lateral misalignments, as is recited in independent claims 30, 35, and 44.

Although Forsmalm teaches that "a certain play is desirable between the gold cylinder and distance member" no details are provided for how this is accomplished. Furthermore, the degree of tolerance mentioned in Forsmalm, i.e. 0.05 - 0.2mm (see col. 4, lines 23-25), is much less than that recited in, for example, claims 31, 32, 35, and 44 of the present application. The Office Action asserts that "it would have been obvious to one having ordinary skill in the art at the time of the invention to provide greater lateral movement to allow for greater degree of correction" (Office Action, p. 5); however, since the goal of Forsmalm is to reduce or eliminate errors that can occur during the impressioning process (see column 4, lines 25-28), the resulting prosthesis would have better alignment and thus would need less rather than more correction during placement

of the prosthesis onto the implant(s). Consequently, the skilled artisan would have had no reason or motivation to increase the degree of lateral movement available during the placement process. If anything, the skilled artisan would be more inclined to reduce, rather than increase the degree of lateral play since one of the benefits of the Forsmalm method is that less lateral correction is needed during placement.

With respect to instant claim 48, which is directed to an impression coping, the Office Action asserts that Forsmalm in Figure 2b teaches an impression coping for taking an impression of a dental implant or implant assembly that "is capable of interfacing with the implant or implant assembly to form a flat to flat interface" (Office Action, p. 7). However, the interface between the impression component (1) and the implant component (9) in Figure 2b clearly includes interlocking projections and recesses and thus does not appear to be a flat to flat interface. Claim 48 is, therefore, also patentable over Forsmalm.

Furthermore, since the apparatus depicted in Forsmalm is for taking impressions rather than for attachment of a dental prosthesis onto implants in the mouth, Forsmalm is not properly combinable with the various secondary references cited by the Examiner, which are directed to different kinds of assemblies for fastening the prosthesis to the implant(s). The secondary references thus cannot be said to compensate for the deficiencies of Forsmalm. The claimed invention is, therefore, patentable over these references.

### Rejections of under 35 U.S.C. § 103 citing Rassoli

Claims 49-50 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Rassoli (U.S. Patent No. 5,662,473). Claim 51 was rejected as being unpatentable over Rassoli in combination with Gordon (U.S. Patent No. 5,733,122). The Office Action asserts that the claimed invention is obvious, because Rassoli discloses a burn-out cylinder comprising a proximal end with a flat surface that interfaces with an implant. Applicants respectfully disagree.

Rassoli describes a burn-out cylinder that includes a metal base (10) and a plastic abutment pattern (11) (see Figure 1). The metal base (10) of the burn-out cylinder interfaces with the implant (12). This metal base has surface features that engage with the hexagonal head (14) of the implant (12), and thus this interface is not a flat surface. The flat surface referred to by the Examiner is not located at the interface between the burn-out cylinder and the implant, but rather is located between the metal base (10) and the plastic abutment pattern (11). Specifically, the Office Action refers to Figure 5 of Rassoli, which shows that the abutment pattern (11) that has a mounting flange (40) with a flat surface (41). However, as can be seen in Figure 9 of Rassoli, this flat surface (41) does not interface with the implant (12). Instead it is the metal base (10) that engages with the hexagonal head (14) of the implant (12). Also, it is clear from Figure 1 of Rassoli that the metal base (10) is part of the burn-out cylinder and not part of the implant (12). Thus, the flat surface identified by the examiner is situated between two different

parts of the burn-out cylinder (i.e. the abutment (11) and the metal base (10)); it is not

located at the interface between the burn-out cylinder and the implant, as is recited in

claim 49. Since Rassoli fails to teach or suggest a flat-to-flat interface between the burn-

out cylinder and the implant, claim 49 and its dependent claims are patentable over this

reference.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the

Application is now in condition for allowance and such action is respectfully requested.

Transmitted herewith is a Petition to extend the period for replying to the Office

action for one month, to and including April 20, 2009, as April 18, 2009 falls on a

Saturday.

If there are any charges or any credits, please apply them to Deposit Account No.

03-2095.

Respectfully submitted,

Date: 20 April 2009

James D. DeCamp

Clark & Elbing LLP 101 Federal Street Boston, MA 02110

Telephone: 617-428-0200 Facsimile: 617-428-7045